LACTATED RINGERS - sodium chloride, sodium lactate, potassium chloride and calcium chloride injection, solution
Baxter Healthcare Corporation

DESCRIPTION

Lactated Ringer's Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

Table 1	Size (mL)	Composition (g/L)				Osmolarity (mOsmol/L) (calc)	pH	Ionic Composition (mEq/L)					Caloric Content (kcal/L)
		Sodium Chloride, USP, (NaCl)	Sodium Lactate, ($C_3H_5NaO_3$)	Potassium Chloride, USP, (KCl)	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)			Sodium	**Potassium**	Calcium	Chloride	Lactate	
Lactated Ringer's Injection, USP	250 500 1000	6	3.1	0.3	0.2	273	6.5 (6.0 to 7.5)	130	**4**	2.7	109	28	9

The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

Lactated Ringer's Injection, USP has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.
Lactated Ringer's Injection, USP produces a metabolic alkalinizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

INDICATIONS AND USAGE

Lactated Ringer's Injection, USP is indicated as a source of water and electrolytes or as an alkalinizing agent.

CONTRAINDICATIONS

None known

WARNINGS

Lactated Ringer's Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.
Lactated Ringer's Injection, USP should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.
Lactated Ringer's Injection, USP should be used with great care in patients with metabolic or respiratory alkalosis. The administration of lactate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.
Lactated Ringer's Injection, USP should not be administered simultaneously with blood through the same administration set because of the likelihood of coagulation.
The intravenous administration of Lactated Ringer's Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.
In patients with diminished renal function, administration of Lactated Ringer's Injection, USP may result in sodium or potassium retention.
Lactated Ringer's Injection, USP is not for use in the treatment of lactic acidosis.

PRECAUTIONS

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Lactated Ringer's Injection, USP must be used with caution. Excess administration may result in metabolic alkalosis.

Caution must be exercised in the administration of Lactated Ringer's Injection, USP to patients receiving corticosteroids or corticotropin.

Pregnancy

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with Lactated Ringer's Injection, USP. It is also not known whether Lactated Ringer's Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Lactated Ringer's Injection, USP should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness of Lactated Ringer's Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of Lactated Ringer's Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

Do not administer unless solution is clear and seal is intact.

ADVERSE REACTIONS

Allergic reactions or anaphylactoid symptoms such as localized or generalized urticaria and pruritis; periorbital, facial, and/or laryngeal edema; coughing, sneezing, and/or difficulty with breathing have been reported during administration of Lactated Ringer's Injection, USP. The reporting frequency of these signs and symptoms is higher in women during pregnancy.

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

All injections in VIAFLEX plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED

Lactated Ringer's Injection, USP in VIAFLEX plastic container is available as follows:

Code	Size (mL)	NDC
2B2322	250	0338-0117-02
2B2323	500	0338-0117-03
2B2324	1000	0338-0117-04

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINER

WARNING: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

To Open

Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

1. Suspend container from eyelet support.
2. Remove plastic protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

WARNING: Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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